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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,157	06/08/2001	David H. McDaniel	509582000110	6918

7590

07/22/2003

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EXAMINER

MENDEZ, MANUEL A

ART UNIT	PAPER NUMBER
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3763

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DATE MAILED: 07/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding:

Office Action Summary

Application No.

09/876,157

Applicant(s)

MCDANIEL, DAVID H.

Examiner

Manuel Mendez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1, drawn to, inter alia, applying an active agent to the skin comprising injecting the active agent into the skin, the active agent comprising at least one of Vitamin C....and anesthetic substance, classified in class 604.
- II. Claim 2, drawn to, inter alia, applying an active agent to the skin, modifying at least portion of the stratum corneum substantially prior to the step of exposing the skin to ultrasound, wherein the step comprises at least one of the steps of, removing at least a follicular plug, removing at least skin debris, and removing at least a portion of the stratum corneum, wherein the active agent comprises at least one of human fibroblasts....and anesthetic substance, classified in class 604.
- III. Claim 3, drawn to inter alia, a method for enhancing the transport of an active agent through mammalian skin wherein the stratum corneum is characterized by a structure, a function, a thickness and a permeability and wherein the step of modifying at least a portion of the stratum corneum comprises at least one of the steps of stripping, removing, thinning and diminishing at least one of the structure, function, thickness and permeability of the stratum corneum by at least one of a mechanical,

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abrasive, photo acoustic, ablative, thermal chemical, abrasive, and
eximatic method, class 604.

- IV. Claim 4, drawn, inter alia, the step of modifying at least a portion of the stratum corneum comprising at least one of the steps of solvent stripping, tape stripping, scrubbing, laser ablation, laser vaporization, chemical peeling, micro dermabrasion, and laser treatment using high peak power, short pulse duration laser, classified in class 604.
- V. Claim 5-6, drawn to, inter alia, the step of modifying at least a portion of the stratum corneum comprising the step of applying an enzyme peel, classified in class 604.
- VI. Claim 7-11, drawn to, inter alia, the step of applying an active agent to the skin comprises at least one of inserting, injecting, and placing fibroblasts into the skin associated with a collagen, a synthetic matrix or a bioengineered matrix, classified in class 604.
- VII. Claim 12-16, drawn to, inter alia, the steps of modifying at least a portion of the stratum corneum, and at least one of inserting, injecting, and placing fibroblasts into the skin associated with a collagen, a synthetic matrix or a bioengineered matrix, classified in class 604.
- VIII. Claim 17-19, drawn to the steps of, inter alia, exposing the skin to light, exposing the skin to ultrasound, and applying an active agent to the skin comprising injecting the active agent into the skin, classified in class 604.

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- IX. Claim 20-36, drawn to the steps of, inter alia, exposing the skin to light, exposing the skin to ultrasound, applying an active agent to the skin, and removing at least a follicular plug from the stratum corneum, removing at least skin debris from the stratum corneum, and removing at least a portion of the stratum corneum, classified in class 604.
- X Claim 37-39, drawn to inter alia, exposing the skin to light, and applying an active agent to the skin, wherein the step of applying an active agent to the skin comprises injecting the active agent into the skin, classified in class 604.
- XI. Claim 40-56, drawn to, inter alia, exposing the skin to light, applying an active agent to the skin, and removing at least a follicular plug from the stratum corneum, removing at least skin debris from the stratum corneum, and removing at least a portion of the stratum corneum, classified in class 604.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different Groups of claims represent different inventions not capable of use together, and having different modes of operation, different functions, and effects. The Groupings above briefly state the different functions and modes of

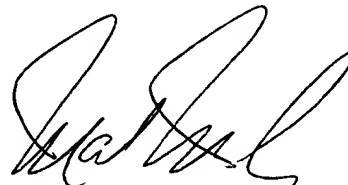
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operation of each and every group. Applicant is respectfully requested to select for prosecution of the groups presented by the examiner.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-308-2221. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

A handwritten signature in black ink, appearing to read 'Manuel Mendez', with a stylized, flowing script.

Manuel Mendez
Primary Examiner
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July 21, 2003